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Risk indicators for mucositis and peri-implantitis: results from a practice-based cross-sectional study

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ABSTRACT

Purpose: This practice-based cross-sectional study aimed to investigate whether common risk indicators for peri-implant diseases were associated with peri-implant mucositis and peri-implantitis in patients undergoing supportive implant therapy (SIT) at least 5 years after implant restoration.

Methods: Patients exclusively restored with a single implant type were included. Probing pocket depth (PPD), bleeding on probing (BOP), suppuration, and radiographic bone loss (RBL) were assessed around implants. The case definitions were as follows: peri-implant mucositis: PPD ≥ 4 mm, BOP, no RBL; and peri-implantitis: PPD ≥ 5 mm, BOP, RBL ≥ 3.5 mm. Possible risk indicators were compared between patients with and without mucositis and peri-implantitis using the Fisher exact test and the Wilcoxon rank-sum test, as well as a multiple logistic regression model for variables showing significance ($P < 0.05$).

Results: Eighty-four patients with 169 implants (observational period: 5.8 ± 0.86 years) were included. A patient-based prevalence of 52% for peri-implant mucositis and 18% for peri-implantitis was detected. The presence of 3 or more implants (odds ratio [OR], 4.43; 95 confidence interval [CI], 1.36–15.05; $P = 0.0136$) was significantly associated with an increased risk for mucositis. Smoking was significantly associated with an increased risk for peri-implantitis (OR, 5.89; 95% CI, 1.27–24.58; $P = 0.0231$), while the presence of keratinized mucosa around implants was associated with a lower risk for peri-implantitis (OR, 0.05; 95% CI, 0.01–0.25; $P < 0.001$).

Conclusions: The number of implants should be considered in strategies to prevent mucositis. Furthermore, smoking and the absence of keratinized mucosa were the strongest risk indicators for peri-implantitis in patients undergoing SIT in the present study.

Keywords: Peri-implantitis; Prevalence; Risk; Smoking

INTRODUCTION

If optimal plaque control is not achieved adjacent to dental implants, inflammation will occur. Peri-implant mucositis has been demonstrated to be a reversible inflammatory

Author Contributions

Conceptualization: Sven Rinke; Data curation: Marc Nordlohne; Formal analysis: Marc Nordlohne, Andreas Leha, Gerhard Schmalz, Sven Rinke; Investigation: Marc Nordlohne, Dirk Ziebolz; Methodology: Dirk Ziebolz, Stefan Renvert, Sven Rinke; Project Administration: Dirk Ziebolz; Writing - original draft: Marc Nordlohne, Gerhard Schmalz; Writing - review & editing: Dirk Ziebolz, Stefan Renvert, Andreas Leha, Sven Rinke.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

condition in the vicinity of dental implants, whereas peri-implantitis is characterized by loss of the implant-surrounding bone [1]. The prevalence of peri-implant diseases is high, and peri-implant mucositis and peri-implantitis have been reported to occur in 43% and 22% of patients with implants, respectively [2].

To avoid peri-implant diseases, regular and comprehensive maintenance after implant placement is necessary and can be successfully applied [3-5]. Furthermore, an important advantage of the prevention of peri-implantitis is cost-effectiveness [6]. Accordingly, supportive implant therapy (SIT) as part of the regular care of patients who receive dental implant restoration appears to be indicated as a logical consequence. Nonetheless, peri-implant inflammation can occur even in patients who receive regular maintenance, albeit less frequently [7].

A potential cause of the persistence of peri-implant mucositis and peri-implantitis despite SIT could be the presence of different risk indicators, which have been repeatedly discussed in the literature and presented in recent review articles [8-10]. Several risk indicators are presumed to be relevant for peri-implant inflammation, including the presence of keratinized soft tissue, the regularity of supportive therapy, periodontal disease history, smoking habits, underlying systemic diseases, and further parameters [8-10]. In particular, smoking and a history of periodontal disease have been repeatedly discussed [8-13].

Accordingly, the present study was performed to assess the prevalence of peri-implant mucositis and peri-implantitis, as well as the potential associations of different risk indicators with peri-implant diseases. For this goal, only patients undergoing SIT at a private dental practice were included. The aim of this practice-based cross-sectional study was to investigate whether common risk indicators for peri-implant diseases were associated with peri-implant mucositis and peri-implantitis in these patients. It was hypothesized that smoking, absence of keratinized mucosa, and history of periodontitis would be risk indicators for peri-implantitis in patients with fixed implant restorations undergoing SIT at a private dental practice.

MATERIALS AND METHODS

Study design

The current study was performed as a clinical single-center practice-based cross-sectional study with additional retrospective data collection. The study protocol was approved by the Ethics Committee of the University Leipzig (No. 080-16-14032016). All patients were informed verbally and in writing about the study and provided written informed consent.

Patients

Patients who were exclusively restored with the same type of dental implants (Neoss GmbH, Cologne, Germany) by a general dentist at a private dental practice in a mid-sized town (Weilburg, Germany) between January 1, 2007 and December 31, 2010 were asked to voluntarily participate in the study.

Patients who met the following criteria were included:

- Age between 18 and 75 years at the time of implant placement
- Attendance at supportive implant therapy at least once a year (SIT)
- Edentulous or partially dentate patients with a fixed superstructure and a functional period of the final prosthetic restoration of at least 60 months

- Panoramic radiograph immediately after surgery
- Panoramic radiograph within 6 months prior to data acquisition
- Periodontal examination (probing pocket depth [PPD] and bleeding on probing [BOP]) at 4 sites per tooth/implant within 6 months prior to data acquisition
- Complete medical history, including information on smoking/nonsmoking

Patients were excluded for the following reasons:

- Aggressive periodontitis
- Not undergoing SIT
- Inadequate radiograph
- No osseointegration of the implant
- Disagreement to participate in the study
- Other missing data
- Death of the patient

Based on the available patient records, data regarding age, sex, diabetes mellitus, and smoking habits were collected. A patient was considered a smoker if he/she reported smoking ≥ 10 cigarettes a day. Patients who did not report a smoking habit during the study period were considered nonsmokers. Individuals who had stopped smoking or smoked fewer than 10 cigarettes a day were not included in the analysis of smoking as a risk indicator [12]. Patients' history of periodontitis was assessed. Furthermore, implant-specific parameters, such as the time point of implant insertion, time point of prosthetic restoration and regular or irregular attendance at SIT visits in accordance with Rinke et al. [13], were assessed using patients' records.

Oral examination

Examination of remaining teeth

A periodontal examination was performed at each recall appointment to assess the overall burden of periodontal disease and/or the patient's need for periodontal treatment at the remaining teeth. The PPD and BOP were assessed at 4 measurement points per tooth using a periodontal probe (PCP 15, Hu-Friedy, Chicago, IL, USA), [13]. Furthermore, the clinical attachment loss (CAL) was recorded as the distance between the cemento-enamel junction and the bottom of the periodontal pocket. The need for periodontal treatment was defined in accordance with a Periodontal Screening and Recording (PSR) index score of 3 or 4 (PPD > 3.5 mm) [14]. For each patient, the maximum value of the PSR index was used to classify their need for treatment. Specifically, patients with PSR index scores of ≤ 2 were classified as not needing periodontal treatment, while patients with maximum PSR index scores of 3 or 4 were classified as needing periodontal treatment.

Examination of implants

Similarly, a millimeter-scale periodontal probe (PCP 15, Hu-Friedy) was used to measure the PPD at 4 sites per implant (mesio-buccal, disto-buccal, mesio-oral, and disto-oral), and BOP was documented 30 seconds after probing. Furthermore, the presence/absence of keratinized mucosa was assessed on the mid-buccal area of every implant site. Differences in color, texture, and mobility served as markers for mucogingival junction detection (presence: > 0.5 mm of keratinized mucosa, absence: ≤ 0.5 mm of keratinized mucosa) [12].

To differentiate between peri-implant mucositis and peri-implantitis, available panoramic radiographs were analyzed. During the survey period, radiographs were obtained only for routine diagnostic purposes.

Case definition

Following a previous study by this working group [13], peri-implant mucositis was defined according to the definition (PPD \geq 4 mm and BOP) of Roos-Jansaker et al. [15]. According to Karoussis et al. [16] and Roos-Jansaker et al. [17], peri-implantitis was diagnosed if progressive bone loss could be determined in addition to the symptoms of peri-implant mucositis. To assess radiographic bone loss (RBL), available panoramic radiographs (Planmeca Promax 2D, Planmeca Oy, Helsinki, Finland) obtained after functional periods ranging from 5 to 7 years were used and analyzed after calibrating the length of each implant with the respective software (Romexis, Planmeca Oy).

The distance between the implant shoulder and marginal bone level was measured at the mesial and distal aspect of each implant. The site with the most pronounced bone loss was chosen to represent each patient. Postoperative radiographs were used to assess the original bone level around the implant. According to the original protocol for the implant system used in this study, the implant shoulder should be placed in level with the alveolar crest. Implants with a supracrestally placed implant shoulder, which violated the surgical protocol, were excluded from this study. Given that no radiographs at the time of functional loading were available, the following definition of peri-implantitis was used: bone level located at least 3.5 mm apically of the implant shoulder on the last available radiograph in conjunction with BOP [18].

All radiographs were read by the same calibrated operator (S.R.). Radiographs from 12 patients with 39 implants were selected for a second analysis of the peri-implant bone level to assess intraexaminer variability [13]. These radiographs were chosen using a table of random numbers. In 89% of the analyzed implants, the intraexaminer analysis demonstrated a difference of the measurements of 0.5 mm, whereas a measurement difference of 0.5–1.0 mm was obtained for the remaining implant sites.

Supportive therapy

The supportive treatment for all patients at each appointment (at least once a year) included an assessment of the gingival bleeding index [19] and plaque index (plaque control record) [20]. The patients were reinstructed regarding oral hygiene measures and remotivated to perform effective individual plaque control, and professional tooth and implant cleaning was performed.

At least once per year, dental status and PPD measurements were obtained at 4 sites per tooth or implant, and BOP was documented 30 seconds after probing. Sites exhibiting a PPD of 4 mm and BOP, as well as sites with a PPD \geq 5 mm, were scaled subgingivally using ultrasonic and hand instruments for teeth or a special ultrasonic tip (Kavo Sonicflex Implant, Kavo Dental GmbH, Biberach, Germany) for implants, followed by manual instrumentation with titanium curettes for implants.

During the first year after implant insertion, SIT was recommended at 3-month intervals. In patients with stable, noninflamed conditions, a 6-month interval was employed thereafter. Patients with a habit of smoking and/or a history of periodontitis, as well as those exhibiting a plaque index of $>$ 35%, were recalled at 3-month intervals for SIT. When a plaque index $<$ 20% was established at 3 consecutive SIT appointments, the appointment interval was extended to 6 months. A patient who did not exceed the recommended intervals for SIT by more than 100% was classified as having regular SIT attendance. Patients who exceeded the recommended intervals by more than 100% were classified as having irregular SIT attendance [21].

Statistical analysis

Possible risk indicators were compared between patients with and without a diagnosis of peri-implantitis and peri-implant mucositis using the Fisher exact test for categorical variables. Otherwise, the Wilcoxon rank-sum test was used. Therefore, this study was limited to a patient-based evaluation of the endpoints of peri-implant mucositis and peri-implantitis. Risk indicators that demonstrated significant differences were combined in a multiple logistic regression model to assess their effect on each dependent variable (peri-implantitis/mucositis). The significance level was set to $\alpha=5\%$ for all statistical tests. All analyses were performed with the statistical software R (version 3.1.2, www.r-project.org).

RESULTS

Patients

Of 123 partially edentulous patients treated with the same implant system between January 2007 and June 2010, 84 patients with 169 implants met all the inclusion criteria and were willing to participate in the present study (Table 1). The mean age of the patients was 51.57 ± 13.05 years, and the median time after implant insertion was 6.1 years (25th/75th percentile: 5.5 years/7.0 years). The patients' characteristics are presented in Table 2. Moreover, 67% of the patients regularly attended SIT without exceeding the proposed risk-oriented intervals by greater than 100%. The remaining patients attended SIT irregularly (at least once a year).

Peri-implant mucositis and peri-implantitis were detected in 52% and 18% of the patients, respectively (Table 2). In 5 patients (3 smokers, 2 nonsmokers), peri-implantitis was diagnosed prior to the clinical follow-up examination of the present study. All patients received surgical treatment consisting of an open-flap debridement, as well as mechanical and chemical (5% hydrogen peroxide) implant decontamination. Systemic antibiotic therapy (Clindasaar, MIP Pharma GmbH, Blieskastel, Germany) was associated with the treatment. No regenerative therapy was performed. In 3 patients, progression of peri-implant bone loss was determined to have occurred during the course of the present study. At the time of the clinical follow-up examination, 2 of the 169 implants (1.2%) had been lost since placement. One failure was related to an implant fracture, and the second was caused by a progression of peri-implant bone loss.

Table 1. Number of included and excluded participants and distribution of the exclusion categories

Variable	Value
Total No. of patients	123
No. of included participants	84
No. of excluded participants	39
Reasons for exclusion	
Aggressive periodontitis	2
No supportive implant therapy	9
Inadequate radiograph	10
No osseointegration of implant	3
Disagreement to participate in the study	11
Other missing data (e.g., medical history, periodontal status)	3
Death of the patient	1

Table 2. Patients' characteristics

Variable	Value
Age in years	51.57±13.05
Time since implant insertion (yr)	6.1 (5.5/7.0)
Place of residence	
Urban	37 (44)
Rural	47 (56)
Employment status	
Employed/self-employed	65 (77)
Unemployed/retired	19 (23)
Sex	
Male	36 (43)
Female	48 (57)
Prosthetic usage period	
5.0–5.9 years	39 (47)
6.0–6.9 years	22 (26)
7.0–7.9 years	23 (27)
Smoking	
No	60 (71)
Yes	24 (29)
Diabetes mellitus	
No	79 (94)
Yes	5 (6)
History of periodontitis	
No	72 (86)
Yes	12 (14)
Regular SIT attendance	
No	28 (33)
Yes	56 (67)
Overall periodontal treatment need (PSI ≥3)	
No	40 (48)
Yes	44 (52)
Presence of keratinized soft tissue	
No	20 (24)
Yes	64 (76)
Peri-implant disease	
Healthy	25 (30)
Mucositis	44 (52)
Peri-implants	15 (18)
No. of implants	
1	44 (52)
2	21 (25)
≥3	19 (23)
Bleeding on probing at implant	
No	34 (40)
Yes	50 (60)
Pocket depth ≥4 mm at implant	
No	14 (17)
Yes	70 (83)
Bone loss ≥3.5 mm at implant	
No	69 (82)
Yes	15 (18)

Values are given as number (%), the mean±standard deviation or the median (25%/75% percentiles). SIT: supportive implant therapy.

Analysis of risk indicators for peri-implant mucositis

In the univariate analysis, only the number of implants was a significant risk indicator associated with peri-implant mucositis ($P=0.02$). More specifically, a higher number of implants (2 and ≥3) was associated with peri-implant mucositis. Smoking ($P=0.81$), history of periodontitis ($P=0.36$) and need for periodontal treatment (PSI ≥3 at the time of the clinical evaluation; $P=0.13$) as well

Table 3. Univariate analysis of potential risk indicators for the presence of mucositis

Variable	Healthy (n=40)	Mucositis (n=29)	P value
Age (years)	49.45±12.85	53.5±13.07	0.10
No. of implants			0.02
1	27 (68)	11 (38)	
2	8 (20)	9 (31)	
≥3	5 (12)	9 (31)	
Time since implant insertion	6.2 (5.6/7.1)	5.9 (5.5/6.6)	0.28
Diabetes			0.36
No	39 (98)	27 (93)	
Yes	1 (2)	2 (7)	
Sex			0.66
Male	16 (40)	14 (48)	
Female	24 (60)	15 (52)	
Presence of keratinized soft tissue			0.21
No	7 (17)	3 (10)	
Yes	33 (83)	26 (90)	
Overall periodontal treatment need (PSI ≥3)			0.13
No	23 (58)	21 (72)	
Yes	17 (42)	8 (28)	
Regular SIT attendance			0.36
No	11 (27)	12 (41)	
Yes	29 (73)	17 (59)	
Smoking			0.81
No	28 (70)	25 (86)	
Yes	12 (30)	4 (14)	
Prosthetic usage period in years			0.99
5.0–5.9	16 (40)	17 (59)	
6.0–6.9	11 (28)	5 (17)	
7.0–7.9	13 (32)	7 (24)	
History of periodontitis			0.36
No	36 (90)	22 (76)	
Yes	4 (10)	7 (24)	

Mean±standard deviation or median (25th/75th percentiles) of numerical variables and the absolute relative frequency of categorical variables are presented separately for patients with and without mucositis. The last column represents the P value of the Wilcoxon rank-sum test and Fisher exact test. Significant results are highlighted in bold (significance level $P<0.05$).

SIT: supportive implant therapy.

as irregular attendance at SPT ($P=0.36$) and the presence of keratinized mucosa around implants ($P=0.21$) were not associated with an increased risk for peri-implant mucositis (Table 3). The number of implants also remained a statistically significant factor in the multivariate analysis. Logistic regression analysis demonstrated that the presence of 3 or more implants (odds ratio [OR], 4.43; 95% confidence interval [CI], 1.36–15.05; $P=0.0136$) was associated with an increased risk for peri-implant mucositis (Table 4).

Table 4. Results of logistic regression for the dependent variable of mucositis

Mucositis	OR	95% CI	P value
No. of implants (1 vs 2 implants)	2.27	0.76–6.81	0.1422
No. of implants (1 vs ≥3 implants)	4.53	1.36–15.05	0.0136
Presence of keratinized mucosa	0.82	0.3–2.29	0.7087
Smoking	0.54	0.18–1.61	0.2693

Variables showing a significant difference between patients with and without mucositis and peri-implantitis were included, along with smoking status and the presence of keratinized mucosa. Significant results are highlighted in bold (significance level $P<0.05$).

OR: odds ratio, CI: confidence interval.

Table 5. Univariate analysis of potential risk indicators for peri-implantitis.

Variable	No peri-implantitis (n=69)	Peri-implantitis (n=15)	P value
Age (yr)	51.19±13.35	53.33±11.82	0.72
No. of implants			0.42
1	38 (55)	6 (40)	
2	17 (25)	4 (27)	
≥3	14 (20)	5 (33)	
Time since implant insertion	6.1 (5.5/7.0)	6.3 (5.9/6.5)	0.93
Diabetes			0.22
No	66 (96)	13 (87)	
Yes	3 (4)	2 (13)	
Sex			0.99
Male	30 (43)	6 (40)	
Female	39 (57)	9 (60)	
Presence of keratinized mucosa			<0.001
No	10 (14)	10 (67)	
Yes	59 (86)	5 (33)	
Overall periodontal treatment need (PSI ≥3)			0.40
No	31 (45)	9 (60)	
Yes	38 (55)	6 (40)	
Regular SIT attendance			0.99
No	23 (33)	5 (33)	
Yes	46 (67)	10 (67)	
Smoking			0.03
No	53 (77)	7 (47)	
Yes	16 (23)	8 (53)	
Prosthetic usage period in years			0.27
5.0–5.9	33 (48)	6 (40)	
6.0–6.9	16 (23)	6 (40)	
7.0–7.9	20 (29)	3 (20)	
History of periodontitis			0.68
No	58 (84)	14 (93)	
Yes	11 (16)	1 (7)	

Mean±standard deviation or median (25th/75th percentiles) of numerical variables and the absolute relative frequency of categorical variables are presented separately for patients with and without peri-implantitis. The last column represents the P value of the Wilcoxon rank-sum test and Fisher exact test. Significant results are highlighted in bold (significance level $P<0.05$)
SIT: supportive implant therapy.

Analysis of risk indicators for peri-implantitis

In the univariate analysis, the presence of attached gingiva ($P<0.01$) and smoking ($P=0.03$) were associated with peri-implantitis (Table 5). No significant associations with peri-implantitis were found for history of periodontitis ($P=0.68$), need for periodontal treatment (PSR ≥ 3) at the time of the clinical evaluation ($P=0.40$), or irregular attendance at SIT ($P=1.00$) (Table 5).

In the multivariate analysis, smoking was significantly associated with an increased risk (OR, 5.88; 95% CI, 1.27–24.58; $P=0.0231$) for peri-implantitis, whereas the presence of keratinized mucosa around implants was significantly associated with a lower risk (OR, 0.05; 95% CI, 0.01–0.25; $P<0.001$) (Table 6).

Table 6. Results of logistic regression for the dependent variable of peri-implantitis

Variable	OR	95% CI	P value
Presence of keratinized mucosa	0.05	0.01–0.25	<0.001
Smoking	5.88	1.27–24.58	0.0231
No. of implants (1 vs 2 implants)	0.70	0.12–4.13	0.693
No. of implants (1 vs ≥ 3 implants)	2.22	0.44–11.29	0.337

Variables showing a significant difference without between patients with and without peri-implantitis were included, as well as the number of implants. Significant results are highlighted in bold (significance level $P<0.05$). OR: odds ratio, CI: confidence interval.

DISCUSSION

In the present study, the patient-based prevalence was 52% for mucositis and 18% for peri-implantitis. The presence of 3 or more implants was associated with an increased risk for mucositis. Furthermore, smoking and the absence of keratinized mucosa around implants were associated with an increased risk for peri-implantitis.

The main findings were consistent with the results presented in recent systematic reviews. In a systematic review including 1,497 patients with 6,283 implants, the patient-based prevalence rate for peri-implantitis was 18.8% [22]. Derks et al. [23] reported patient-based prevalence rates of 43% for mucositis and 22% for peri-implantitis. In an analysis of 47 clinical studies with an average clinical follow-up of at least 3 years, a patient-based peri-implantitis prevalence of 19.8% was reported, while the subject-based mucositis prevalence was 46.8% [24]. A similar patient-based peri-implantitis rate (18.5%) based on the evaluation of 29 clinical studies was reported in a more recently published systematic review [25]. These findings are consistent with the results of the present study.

Furthermore, the results of the present study are consistent with the findings of another cross-sectional study using comparable endpoints and diagnostic criteria. In that university-based study, the prevalence of peri-implantitis was 16.4% [12]. In another cross-sectional study with 588 patients, moderate or severe peri-implantitis (bone loss >2 mm) was detected in 14.5% of patients after an average observational period of 9 years [26].

However, the special condition in the current study was patients' attendance at SIT. It has been demonstrated that SIT plays an important role in reducing the prevalence of peri-implant mucositis and peri-implantitis [7]. In other studies that investigated peri-implantitis prevalence in patients undergoing SIT, a lower patient-based prevalence was detected than in the current study. The reported prevalence of mucositis ranges from 36% to 39%, while that of peri-implantitis ranges from 9% to 16% [26,27]. Those studies demonstrated that patients undergoing SIT experienced a lower rate of biological complications, which is in contrast to the findings of the present study. In a previous practice-based study with a similar number of included patients that used the same diagnostic criteria and had a comparable observational period, 44.9% of the patients had peri-implant mucositis, and 11.2% of patients exhibited peri-implantitis; these rates are lower than those observed in the present study [13]. The difference between these results and those of the present study might be attributed to the different minimum observational periods (5 years in the present study compared with 2 years in the 2011 study by Rinke et al.) [13]. Moreover, the study populations differ in terms of the percentage of included smokers (29% in the present study and 19% in the aforementioned study by Rinke et al.) [13]. However, no associations between mucositis or peri-implantitis and irregular SIT were noted in the statistical analysis of the current study. A possible explanation for this may be related to the skewed distribution of patients attending SIT on a regular basis and those attending irregularly.

The treatment and prevention of peri-implant mucositis are key factors in preventing peri-implantitis [28]. Accordingly, the risk indicators for peri-implant mucositis are highly relevant. A recent review article reported that the few studies that assessed risk indicators for peri-implant mucositis have demonstrated that plaque accumulation and smoking should be considered as risk indicators [10]. It is therefore surprising that neither smoking nor regular attendance at SIT were risk indicators for peri-implant mucositis in

the current study. Only the presence of 3 or more implants was associated with an increased prevalence of peri-implant mucositis. Recent studies have demonstrated that the number of implants is associated with peri-implant diseases [12,23,29,30]. This association might be attributed to difficulties in performing adequate oral hygiene around multi-unit or splinted restorations, which are typically used in cases with multiple implants per patient [31]. This consideration applies to the patients with multiple implants in the present study, as they were predominantly restored with cemented multi-unit fixed superstructures.

Another possible reason for this association may be that single tooth restorations are placed predominantly due to tooth loss resulting from trauma or endodontic failure or congenital missing teeth. Multiple implant-based restorations or multiunit restorations are more likely to be used in patients with a history of periodontitis, which has been demonstrated to be a risk indicator for biological complications [11,12,32]. However, the present study was not able to confirm this association for peri-implantitis. A possible explanation can be attributed to the lower number of events for the endpoint of peri-implantitis than for the endpoint of mucositis and the limited number of patients included in the present study.

Based on the findings of the present study, the presence of keratinized mucosa around implants was associated with a lower risk for peri-implantitis, in both univariate and multivariate analyses. The determined OR of 0.05 means that the presence of keratinized mucosa is linked to a 20-fold decreased risk for the occurrence of peri-implantitis. The literature regarding this issue is inconclusive [33]. However, 4 recent cross-sectional studies found similar results to those of the current study [34-37]. Accordingly, a recent systematic review article concluded that the presence of an appropriate amount of keratinized mucosa is necessary for avoiding peri-implant inflammation [38]. These findings support the current study's results. For the interpretation of the results of the present study, it should be considered that the cut-off point for the presence/absence of keratinized mucosa was set at 0.5 mm, while comparable cross-sectional studies rated 2 mm as the limit for an appropriate width of keratinized mucosa [34,35,37]. It should be mentioned that the presence of keratinized mucosa is not a risk indicator, but directly contributes to the reduction of peri-implantitis risk. In a clinical setting, the presence of keratinized mucosa was more reliable than its complete absence. Therefore, the decision was made to assess and analyze the presence of keratinized mucosa, rather than its absence, in the current study.

Furthermore, in the present study, smoking was found to be a strong risk indicator associated with peri-implantitis. Several recently published clinical investigations have reported comparable findings to that of the current study [11,13,39,40]. These findings underscore the possible relevance of habitual smoking as a risk indicator associated with peri-implantitis. Nevertheless, these results should still be interpreted with caution, as recent meta-analyses have concluded that there was evidence for this factor only at a medium to medium-high level [8,9,34].

Furthermore, based on the literature, irregular maintenance and a history of periodontitis are relevant risk indicators [7,8-11,33,41]. However, the current study did not reveal any association between maintenance and a history of periodontitis as risk indicators for peri-implant disease. A possible explanation may be the relatively small study population and the skewed distribution of patients exposed to different risk indicators.

The present study failed to demonstrate an association between regular attendance at SIT and a reduced prevalence rate of peri-implantitis. The results of the present study are

different from those of a previous cross-sectional study using the same case definitions and risk-oriented SIT intervals. In the present study, 13% of the nonsmoking patients were diagnosed with peri-implantitis, whereas only 2.8% of nonsmoking patients exhibited peri-implantitis in the previous study [13]. The most noteworthy difference between these studies is the training and clinical experience of the provider of the SIT. In the study by Rinke and colleagues [13], SIT was provided by a single, well-trained registered dental hygienist with more than 15 years of practical experience. In the present study, SIT was rendered by various dental assistants with different qualifications. It might be hypothesized that the effectiveness of SIT is not only influenced by patient compliance, but also by the qualifications and experience of the dental staff providing SIT. The absence of plaque scores limits the degree to which the efficacy of the SIT visits could be evaluated. This also limits the conclusions regarding the association between SIT visits and the development of peri-implantitis. Further clinical investigations are necessary to evaluate the effects of SIT on the prevalence of peri-implant diseases in a well-maintained patient population.

The major strength of the current study is its design as a practice-based study that included 84 patients restored with 169 implants. Other strengths are that the minimal observational period was 5 years and that the functional period of the restored implants varied only to a comparatively small extent (median 6.1 years; 25th/75th percentiles: 5.5 years/7.0 years). However, the study is limited by its design as a cross-sectional study with a retrospective analysis without a prospective longitudinal assessment. The first main limitation of the retrospective design is that no cause-effect relationship on a longitudinal basis can be determined. Therefore, analytical cross-sectional studies are limited to examining the association between an exposure and a disease. The second limitation of a cross-sectional design involves the selection of the study population, which may bias the results. To select a representative source population in the present study, data were generated from a typical setting in a private dental office in a mid-size town in Germany with all clinical procedures performed by a general practitioner.

The present study analyzed possible risk indicators only at the patient level. A separate analysis of specific risk factors (e.g., the presence of keratinized mucosa) at the implant level would be of interest. However, this type of analysis would not be meaningful from the statistical point of view, as it would carry a high risk of being underpowered, which represents another limitation of the study. Moreover, the majority of parameters were patient-specific risk indicators (sex, age, smoking habit, history of periodontitis, adherence with supportive therapy, number of implants per patient, and diabetes). Accordingly, the patient-level analysis seems meaningful from a clinical perspective.

The present study evaluated implants from a single manufacturer. Therefore, potential implant-specific risk indicators (e.g., design and surface roughness) could not be analyzed. Furthermore, the inclusion of only patients with a fixed superstructure must be considered as a potential source of bias. Another limitation is that the statistical analysis was limited to a patient-based analysis; therefore, only patient-specific risk indicators could be analyzed.

Nevertheless, the present study makes a valuable contribution to the evaluation of patient-related risk indicators associated with peri-implantitis and peri-implant mucositis in the typical setting of a private practice after a prolonged period of clinical services.

Future prospective clinical trials are needed to confirm the findings of the present study in a more controlled setting with a larger population and a longer observational period.

In conclusion, the number of implants was associated with an increased risk for peri-implant mucositis. This indicates the need for particularly careful attention to patients who have higher numbers of implants to prevent peri-implant mucositis. Furthermore, missing keratinized mucosa and smoking were risk indicators for peri-implantitis in patients under SIT in a private practice setting 5 years after implant restoration. Accordingly, increased information, motivation for self-performed oral hygiene measures, and professional care are essential to prevent disease development in smoking patients in whom dental implants are placed.

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